MIAMI-DADE COUNTY, FLORIDA

OFFICE OF STRATEGIC BUSINESS MANAGEMENT
RYAN WHITE TITLE I PROGRAM
111 N.W. 1st Street, 22nd Floor
MIAMI, FLORIDA 33128-1900
(305) 375-4742
FAX (305) 375-4454

May 11, 2005

Dear Ryan White Title I Service Provider:

RE: Revised Letter of Medical Necessity for Testosterone Gel (Androgel® 1%, Testim® 1%)

Enclosed for your information and distribution is a **revised** Ryan White Title I Letter of Medical Necessity for Testosterone Gel (Androgel® 1%, Testim® 1%) with an effective date of May 9, 2005.

PLEASE NOTE THE FOLLOWING CHANGE:

- Testim® 1% has been added to the Ryan White Letter of Medical Necessity for Testosterone Gel (Androgel® 1%), which is an equivalent product currently available in the Ryan White Title I Prescription Drugs Formulary.

The implementation of this Letter of Medical Necessity was approved by the Miami-Dade HIV/AIDS Partnership on May 9, 2005 and revisions were approved by the Medical Care Subcommittee on April 22, 2005. The Letter of Medical Necessity for Testosterone Gel (Androgel® 1%, Testim® 1%) continues to include the following restrictions:

1. This drug is **not** for widespread use and should not be used as an initial first-line treatment. To qualify for Title I coverage, the patient must experience a low serum testosterone level as defined by the current medical guidelines of the Florida Department of Health and Human Services (a testosterone level below normal as measured by the reference lab). Prescribing physicians **MUST** include the patient's most recent testosterone level on the Letter of Medical Necessity submitted for this medication. If this information is not provided, Title I will **not** cover the cost of this medication.

2. A copy of a dated lab report with the testosterone level results **MUST** also be submitted at the time of **initial** referral to correspond with the information provided on the Letter of Medical Necessity. The physician prescribing this medication **MUST** sign the Letter of Medical Necessity attesting to the following:

    a. There is an existing contraindication to the injectable formulation whereby the patient has a history of a medical condition in which the use of the different intramuscular injection sites is contraindicated.
    b. There is a reason as specified on the Letter of Medical Necessity why testosterone replacement with testosterone gel is medically necessary.

3. At the time of **initial** referral, the referring organization must submit the following documentation to the Ryan White Title I prescription drugs provider in order for the patient to receive this medication in a timely manner:

    a. Referral form generated by the Service Delivery Information System (SDIS)
    b. Physician's prescription for this medication
    c. Letter of Medical Necessity for Testosterone Gel (Androgel® 1%, Testim® 1%) signed by the prescribing physician
    d. Copy of dated lab report with testosterone level results

IMPORTANT – please note that the Ryan White Title I Letter of Medical Necessity for Testosterone Gel (Androgel® 1%, Testim® 1%) will be reviewed and revised periodically by the Miami-Dade HIV/AIDS Partnership and/or the Medical Care Subcommittee.

Program staff and clients should be notified immediately of the requirement to use this Letter of Medical Necessity for Testosterone Gel (Androgel ® 1%, Testim® 1%). If further clarification is needed, please contact Theresa Wright-Williams, or myself, at (305) 375-4742.

Sincerely,

Daniel T. Wall
Assistant Director
Office of Strategic Business Management

Enclosure

RYAN WHITE TITLE I PROGRAM
Letter of Medical Necessity to Accompany Initial Prescription for
Testosterone Gel (Androgel® 1%, Testim® 1%)
(MUST ACCOMPANY INITIAL REFERRAL TO THE PHARMACY ALONG WITH A PRESCRIPTION)

Date: _____

As the prescribing physician for _____, who has a diagnosis of low serum testosterone level*, it is my opinion that testosterone replacement with testosterone gel (Androgel® 1%, Testim® 1%) is medically necessary for this patient. The following criteria have been met and required information submitted.

The medication will be utilized to treat low serum testosterone level* **if** the following are met:

1. The patient has a documented history of prior intramuscular (IM) long acting testosterone use for _____ (amount of time).

2. There is an existing contraindication to the injectable formulation whereby the patient has a history of a medical condition in which the use of the different intramuscular injection sites is contraindicated (i.e., infection/abscess at all injection sites). **Please specify the reason for the contraindication** (check the appropriate box):

   ☐ Hemophilia
   ☐ Anticoagulation – patient is on Coumadin
   ☐ Infection/small abscess at injection site until infection resolves
   ☐ Thrombocytopenia

   Please provide the following ***PATIENT INFORMATION***:

DATE parameter measured:	**PARAMETERS**			
	Height:			
	Weight:	Lbs	or	Kg
	Serum Testosterone Level:			

* A testosterone level below normal as measured by the reference lab. Please submit with the **initial** referral and prescription a copy of the dated lab report with testosterone level results.

Sincerely,

_____, M.D.
SIGNATURE

_____ _____
PRINT NAME (Physician) | Florida Medical License # (MEO#)

_____ _____
Patient's 10 digit Medicaid # (if applicable) | Patient's CIS # (assigned by the Ryan White Title I Service Delivery Information System)

Please note: All questions should be addressed to Mr. Daniel T. Wall, Assistant Director, Office of Strategic Business Management, at (305) 375-4742. Requests for information/clarification of a clinical nature will be forwarded by Miami-Dade County to the Miami-Dade HIV/AIDS Partnership Medical Care Subcommittee and/or a qualified member of the Subcommittee.

Pursuant to Article VI, Section 6.4 (H) of the Ryan White Title I service agreement, Miami-Dade County has the right to access all client files (including electronic files), service utilization data, and medical records during on site verification or audit by County personnel and/or authorized individuals to confirm the accuracy of all information reported by the service provider.

Rev. 5/9/05